

Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

1. (currently amended) A method for separating ~~isolating~~ a protein molecule or a population of protein or peptide molecules from high molecular weight molecules and structures, comprising:

- (a) contacting one or more cells comprising ~~cellular sources of~~ protein or peptide molecules with at least one pore-containing matrix, wherein said matrix ~~which substantially~~ retards the flow of high molecular weight molecules ~~[[,]]~~ or structures, and aggregates but does not substantially retard the flow of soluble protein and peptide molecules, and one or more lysis/disruption/permeabilization compositions or compounds in an amount sufficient to lyse, disrupt or permeabilize the cells; and
- (b) subjecting said matrix to conditions that promote the flow of material through said matrix, wherein said conditions are sufficient to allow said protein molecule or said population of protein or peptide molecules to pass through the matrix while said high molecular weight molecules or structures are trapped or bound to said matrix;

thereby separating ~~or substantially separating~~ said protein or peptide molecules from said high molecular weight molecules and structures.

2. (currently amended) The method of claim 1, wherein said high molecular weight molecules or structures are selected from the group consisting of chromosomal DNA, membrane fragments, liposomes, mitochondria, chloroplasts, ribosomes, aggregates of molecules and inclusion bodies ~~further comprising causing the cellular source to release all or a portion of the said protein or peptide molecules.~~

3. (currently amended) The method of claim 1, wherein said matrix is selected from the group consisting of a porous ceramic matrix, a polysaccharide matrix, polyester matrix, a polyolefin matrix, a sintered polyethylene matrix, a nitrocellulose matrix, a cellulose acetate matrix, a nylon matrix, a cellulose matrix and a silica matrix.

4. (currently amended) The method of claim 1, wherein the average size of said pores in said matrix ranges from about 1,000 microns to about 0.1 microns in diameter.

5. (original) The method of claim 4, wherein said pores are from about 500 to about 1 microns in diameter.

6. (original) The method of claim 5, wherein said pores are from about 400 to about 25 microns in diameter.

7. (currently amended) The method of claim 1, wherein said conditions that promote the flow of material through said matrix are selected from the group consisting of addition of an aqueous solution, centrifugation, gravity, vacuum, pressure, and combinations thereof ~~release of the said protein or peptide molecules are accomplished by a lysis/disruption/permeabilization composition or compound.~~

8. (currently amended) The method of claim 1 [[7]], wherein said lysis/disruption/permeabilization composition or said matrix, or both, further comprises one or more detergents.

9. (currently amended) The method of claim 1 [[7]], wherein said lysis/disruption/permeabilization composition or said matrix, or both, further comprises one or more enzymes.

10. (currently amended) The method of claim 9, wherein said enzyme is selected from the group consisting of a nuclease, lyticase, neuraminidase, streptolysin,

cellulysin, mutanolysin, chitinase, glucalase, lysozyme, lysostaphin [[or]] and zymolyase.

11. (currently amended) The method of claim 1, wherein said matrix comprises said one or more lysis/disruption/permeabilization compositions or compounds.

12. (currently amended) The method of claim 38 [[1]], further comprising

(d) passing through said matrix a composition that disrupts and/or solubilizes said high molecular weight molecules or structures, thereby generating solubilized or disrupted protein or peptide molecules;

(e) subjecting said matrix to conditions that promote the elution of soluble material from said matrix, in order to generate an eluate; and

(f) collecting said eluate.

~~(a) contacting said filter with a composition that disrupts and/or solubilizes protein aggregates and/or membrane fragments;~~

~~_____ (b) collecting the solubilized or disrupted protein or peptide molecules.~~

13. (currently amended) The method of claim 12, wherein said composition comprises a detergent, chaotropic ~~chaetropic~~ agent or salt.

14. (currently amended) The method of claim 13, wherein said chaotropic ~~chaetropic~~ agent is urea.

15. (currently amended) The method of claim 1, wherein said contacting of said cells with said matrix and with said one or more lysis/disruption/permeabilization compositions or compounds occurs concurrently ~~further comprising collecting said protein or peptide molecules.~~

16. (currently amended) The method of claim 1, wherein said one or more cells are ~~cellular source is a cell~~ selected from the group consisting of a bacterial cells, a yeast cells, a fungal cells, ~~an~~ animal cells, insect cells, mammalian cells, human cells, a cells infected by a virus, transfected cells and a plant cells.

17. (currently amended) The method of claim 16, wherein said one or more cells are bacterial cells of a genus selected from the group consisting of *Escherichia*, *Bacillus*, *Staphylococcus*, *Agrobacter*, *Streptomyces*, *Pseudomonas*, *Serratia* and *Caryophanon* ~~is an *Escherichia coli* cell.~~

18. (currently amended) The method of claim 16, wherein said one or more cells are insect cells selected from the group consisting of *Drosophila* cells, *Spodoptera* cells and *Trichoplusa* cells ~~yeast cell is a *Sacchomyces* cell.~~

19. (cancelled)

20. (currently amended) A composition for use in isolating a protein or peptide molecule or a population of protein or peptide molecules, said composition comprising:

(a) one or more lysis/disruption/permeabilization compositions or compounds in an amount sufficient to lyse, disrupt or permeabilize cells ~~one or more cellular sources of said protein or peptide molecules; and~~

(b) one or more pore-containing matrices which ~~substantially~~ retard the flow of high molecular weight molecules, structures, and aggregates but do not ~~substantially~~ retard the flow of soluble protein and peptide molecules; ~~and optionally~~

(c) ~~at least one compound or composition that lyses/disrupts/permeabilizes said cellular source.~~

21. (currently amended) An apparatus for extracting and isolating protein or peptide molecules, comprising:

(a) a housing, wherein said housing contains; ~~and~~

~~(b)~~—one or more pore-containing matrices, which ~~substantially~~ retards the flow of high molecular weight molecules[[,]] and structures, ~~and aggregates but does~~ do not ~~substantially~~ retard the flow of said protein and peptide molecules ~~in said container; and;~~

(b) one or more lysis/disruption/permeabilization compositions or compounds; and

(c) at least one composition selected from the group consisting of chromatographic resins that bind proteins or peptides, chromatographic resins that bind impurities, chromatographic resins having bound thereto protein modifying reagents, chromatographic resins having bound thereto enzymes, chromatographic resins having bound thereto nucleic acids, chromatographic resins having bound thereto an enzyme substrate, filters, and compositions ~~eapable of being used for detecting or quantifying~~ which detect or quantify the amount of protein or nucleic acid present in ~~the~~ a sample.

22. (currently amended) The apparatus of claim 21, wherein said housing containing said pore-containing matrix is a tube ~~further comprising a porous solid support.~~

23. (currently amended) The apparatus of claim ~~[[21]]~~ 22, wherein said pore containing matrix divides said tube into ~~[[a]]~~ an upper sample application section and a lower sample collection section.

24. (currently amended) The apparatus of claim 21, wherein said pore containing matrix is provided in a format selected from the group consisting of: an insert, a frit, a plug, a cartridge, [[or]] a swab tip, a membrane, a filter, a bead, and a gel.

25. (currently amended) The apparatus of claim 21, wherein said pore containing matrix is selected from the group consisting of: polyester, polyolefin,

scintered polyethylene, nitrocellulose, cellulose acetate, nylon, cellulose, porous ceramic, silica, polysaccharide, and polymer matrices.

26. (original) The apparatus of claim 21, wherein said pore containing matrix is a solid matrix.

27. (original) The apparatus of claim 21, wherein said pore containing matrix is a semi solid matrix.

28. (currently amended) The apparatus of claim 21, wherein the average size of said pores in said matrix ~~range~~ ranges from about 0.1 to about 10,000 microns in diameter.

29. (original) The apparatus of claim 23, wherein said sample collection section has an access port formed therein.

30. (currently amended) The apparatus of claim 21, wherein said pore containing matrix comprises ~~[[a]]~~ said one or more cell lysis/disruption/permeabilization ~~composition~~ compositions or compounds.

31. (original) The apparatus of claim 30, wherein said cell lysis/disruption/permeabilization composition is selected from the group consisting of a detergent, an enzyme, an inorganic salt, an acid, a base, and a buffering agent.

32. (currently amended) The apparatus of claim 21, wherein said housing is selected from the group consisting of a tube, a bottle, a vial, an ampule, a microspin tube, a well, a column, a mini-column, a multi-well plate, a bag, a box, ~~[[or]]~~ and a carton.

33. (currently amended) A kit ~~for use in isolating a protein or peptide molecule or a population of protein or peptide molecules, said kit~~ comprising the apparatus of claim 21.

34. (currently amended) The kit of claim 33, further comprising at least one composition selected from the group consisting of chromatographic resins that bind proteins or peptides, chromatographic resins that bind impurities, chromatographic resins having bound thereto protein modifying reagents, chromatographic resins having bound thereto enzymes, chromatographic resins having bound thereto nucleic acids, chromatographic resins having bound thereto an enzyme substrate, filters, and compositions ~~capable of being used for detecting or quantifying~~ which detect or quantify the amount of protein or nucleic acid present in the sample.

35. (currently amended) The kit of claim 33, further comprising at least one composition selected from the group consisting of antibodies which bind to the protein or peptides of the invention, substrates for said protein or peptides, ligands for said proteins or peptides, cofactors for said protein or peptides, nucleic acid molecules which bind to said proteins or peptides, inhibitors of said proteins or peptides, enzymes which modify said proteins or peptides, compositions which modify said proteins or peptides, compositions which bind said proteins or peptides, compositions which are bound by said proteins or peptides, and compositions ~~capable of being used for detecting or quantifying~~ which detect or quantify the amount of protein or nucleic acid present in ~~[[the]]~~ a sample.

36. (currently amended) The kit of claim 33, further comprising one or more collection tubes ~~wherein all compositions are contained in one or more fluid channels so that the sample may pass through the at least one pore containing matrix and directly contact the at least one composition of claim 34 or 35 without the need for removal and re-application of the sample.~~

37. (currently amended) The kit of claim 33, further comprising one or more enzymes ~~wherein all compositions are contained in two or more fluid channels or containers such that the sample may be directly applied to the at least one composition of claim 34 or 35, after passing through the at least one pore containing matrix.~~

38. (new) A method for isolating a protein molecule or a population of protein or peptide molecules from a cell comprising said protein molecule or a population of protein or peptide molecules and high molecular weight molecules and structures, comprising:

- (a) contacting said cell with at least one pore-containing matrix, wherein said matrix substantially retards the flow of high molecular weight molecules or structures but does not substantially retard the flow of soluble protein and peptide molecules, and one or more lysis/disruption/permeabilization compositions or compounds in an amount sufficient to lyse, disrupt or permeabilize cells;
- (b) subjecting said matrix to conditions that promote the flow of material through said matrix, wherein said conditions are sufficient to allow said protein molecule or said population of protein or peptide molecules to pass through the matrix while said high molecular weight molecules or structures are trapped or bound to said matrix, in order to generate a flow-through; and
- (c) collecting said flow-through.

39. (new) The apparatus of claim 21, wherein said housing is a 96-well multi-well plate.

40. (new) The kit of claim 37, wherein said enzyme wherein said enzyme is selected from the group consisting of a nuclease, lyticase, neuraminidase, streptolysin, cellulysin, mutanolysin, chitinase, glucalase, lysozyme, lysostaphin or zymolyase.